

DOCKET NO.: 03-02US
Application No.: 10/787,385
Office Action Mailed: 07/31/06

AMENDMENTS TO THE CLAIMS

Please amend this application as described in the Listing of Claims, which will replace all prior versions and listings of claims in the above-referenced application.

LISTING OF CLAIMS

1. (Original) A stable pharmaceutical aqueous solution of cyanocobalamin comprised of cyanocobalamin and water wherein said solution of cyanocobalamin is suitable for intranasal administration, has a viscosity less than about 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin when administered intranasally of at least about 7% relative to an intramuscular injection of cyanocobalamin with the proviso that the solution contains no mercury or mercury compounds.
2. (Original) The aqueous solution of cyanocobalamin of claim 1, wherein the solution is comprised of citric acid, and sodium citrate and water and has a pH of about 4-6.
3. (Original) The aqueous solution of claim 2 wherein the pH of the solution is about 5.
4. (Original) The aqueous solution of claim 2 further comprised of a humectant.
5. (Original) The aqueous solution of claim 4 wherein the humectant is selected from the group consisting of sorbitol, propylene glycol, and glycerin.
6. (Original) The aqueous solution of claim 5 wherein the humectant is glycerin.
7. (Original) The aqueous solution of claim 6 wherein the glycerin is present at a concentration of about 2.23%.
8. (Original) The aqueous solution of claim 2 wherein the solution is further comprised of a preservative.

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9. (Original) The aqueous solution of claim 8 wherein the preservative is selected from the group consisting of benzyl alcohol, chlorobutanol and benzalkonium chloride.

10. (Original) The aqueous solution of claim 9 wherein the preservative is benzalkonium chloride.

11. (Original) The aqueous solution of claim 10 wherein the benzalkonium chloride is present in solution at a concentration of about 0.02%.

12. (Original) The aqueous solution of claim 2 wherein cyanocobalamin is present at about concentration 0.5% percent of total weight, citric acid is present at a concentration of about 0.12%, sodium citrate is present at a concentration of about 0.32%.

13. (Original) The aqueous solution of claim 12 wherein the pH of the solution.

14. (Original) The aqueous solution of claim 12 further comprised of a humectant.

15. (Original) The aqueous solution of claim 14 wherein the humectant is selected from the group consisting of sorbitol, propylene glycol, and glycerin.

16. (Original) The aqueous solution of claim 15 wherein the humectant is glycerin.

17. (Original) The aqueous solution of claim 16 wherein glycerin is present in solution at a concentration of about 2.23%.

18. (Original) The aqueous solution of claim 12 further comprised of a preservative.

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19. (Original) The aqueous solution of claim 18 wherein the preservative is selected from the group consisting of benzyl alcohol, chlorobutanol and benzalkonium chloride.

20. (Original) The aqueous solution of claim 19 wherein the preservative is benzalkonium chloride.

21. (Original) The aqueous solution of claim 20 wherein the benzalkonium chloride is present in solution at a concentration of about 0.02%.

22. (Original) The aqueous solution of claim 1 wherein the solution of cyanocobalamin has at least about 12% bioavailability relative to an intramuscular injection of cyanocobalamin.

23. (Original) A stable pharmaceutical aqueous solution of cyanocobalamin comprised of cyanocobalamin at a concentration of about 0.5% of total weight of solution, citric acid at a concentration of about 0.12%, sodium citrate at a concentration of about 0.32%, glycerin at a concentration of about 2.23%, benzalkonium chloride at concentration of about 0.02% and water wherein said solution of cyanocobalamin is suitable for intranasal administration, has a viscosity less than about 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin when administered intranasally of at least about 7% relative to an intramuscular injection of cyanocobalamin with the proviso that mercury and mercury containing compounds are not present.

24. (Original) A method for administering cyanocobalamin comprised of infusing the nose with an aqueous solution of cyanocobalamin, wherein the solution of cyanocobalamin has a viscosity of less than 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin of about 7% relative to an intramuscular injection of cyanocobalamin, with the proviso that mercury and mercury containing compounds are not present in the solution.

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25. (Original) The method of claim 24 wherein the solution of cyanocobalamin is further comprised of citric acid and sodium citrate wherein the solution has a pH of from about 4-6.
26. (Original) The method of claim 25 wherein the pH of the solution is about 5.
27. (Original) The method of claim 25 wherein cyanocobalamin is present in solution at a concentration of between 0.5-1% by weight.
28. (Original) The method of claim 27 wherein the concentration of cyanocobalamin in solution is about 0.5%.
29. (Original) The method of claim 28 wherein the citric acid is present in solution at a concentration of about 0.12%, and the sodium citrate is present in solution at a concentration of about 0.32%, in water.
30. (Original) A method for administering cyanocobalamin comprised of infusing the nose with an aqueous solution of cyanocobalamin wherein said aqueous solution of cyanocobalamin is comprised of cyanocobalamin at a concentration of about 0.5% of total weight of solution, citric acid at a concentration of about 0.12%, sodium citrate at a concentration of about 0.32%, glycerin at a concentration of about 2.23%, benzalkonium chloride at concentration of about 0.02% and water wherein said solution of cyanocobalamin is suitable for intranasal administration, has a viscosity less than about 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin when administered intranasally of at least about 7% relative to an intramuscular injection of cyanocobalamin, with the proviso that the solution of cyanocobalamin contains no mercury or mercury-containing compounds.
31. (Original) A method for elevating the vitamin B12 levels in the cerebral spinal fluid (CSF) comprising administering intranasally a sufficient amount of a solution of cyanocobalamin so that the average ratio of vitamin B12 in the CSF to that in the blood serum ($B12\text{ CSF}/B12\text{ Serum} \times 100$) is increased to at least about 1.1, wherein said

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aqueous solution of cyanocobalamin is comprised of cyanocobalamin at a concentration of about 0.5% of total weight of solution, citric acid at a concentration of about 0.12%, sodium citrate at a concentration of about 0.32%, glycerin at a concentration of about 2.23%, benzalkonium chloride at concentration of about 0.02% and water wherein said solution of cyanocobalamin is suitable for intranasal administration, has a viscosity less than about 1000 cPs, and wherein said solution of cyanocobalamin has a bioavailability of cyanocobalamin when administered intranasally of at least about 7% relative to an intramuscular injection of cyanocobalamin, with the proviso that the cyanocobalamin solution contains no mercury or mercury-containing compounds.